REMARKS

Status of the Claims

Claims 1-69 are pending. Claims 7, 33, 38-42, 45-49, 52-59, and 63-69 are canceled as being nonelected claims and withdrawn from consideration. Claims 1-6, 8-32, 34-37, 43, 44, 50, 51, and 60-62 are rejected. Claim 1 is amended. Claims 3 and 60 are canceled. No new matter has been added. Reconsideration of the pending claims is respectfully requested.

Amendments to the claims

Claim 1 is amended to incorporate the limitations of dependent claim 3 in the preamble and is drawn to a device to alter or ablate tissue in an individual. The device comprises an abrasive member contacting an abrasive material disposed on said tissue or comprising an abrasive material attached thereon and contacting said tissue, a means to drive the abrasive member at high frequency and the abrasive material (pg. 18, ll. 19-21). Claim 9 is amended to delete magneto-responsive because polypyrrol is response to electric current. Claim 61 is amended to depend directly from dependent claim 19 and further limit the lubricant comprising the abrasive material to glycerol and water. Claim 62 is amended to depend directly from dependent claim 19 and further limit the lubricant comprising the abrasive material as electrically conductive. Claims 3 and 60 are canceled. No new matter is added in these amendments.

The 35 U.S.C. §112 First Paragraph Rejection

Claims 9-12 are rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. This rejection is respectfully traversed.

The Examiner states that the specification is not enabling for how a material, such as polypyrrol, filings or Nitinol functions as a means for driving an applicator. The driving means in the instant application causes high frequency vibration of the abrasive member on the tissue surface (pg. 19, ll. 2-4). Polypyrrol is a highly conductive electrolytic polymer used as an actuator to provide movements within a 100

μm to a centimeter range with moderate power up-take. The effect of movement is based on a reversible controlled change of volume in the presence of an current. Polypyrrol actuators can generated great specific power even after miniaturization and have several known medical applications.

Electro- or magneto-rheologic materials are known in the art as fluids that contain microscopic-sized metal particles or filings. Normally, they flow like water, but when an electric current or a magnetic field is applied to the metal particles or filings, they become conductive and the viscous fluid becomes instantaneously stiff and, depending on how the fluid is confined within a device, can extend or protrude in its stiffened state to drive movement. The process also is instantaneously reversible when the electric current or magnetic field is reversed.

Nitinol is a shape-memory alloy actuator wire made of nickel and titanium that contracts when electrically heated and is known in the art to have medical applications. When conducting an electric current, the wire heats and shortens to its "unstretched" shape. This lengthening and shortening action can be used to create movement to drive the applicator.

All these materials are standard and known in the art and known to have medical applications. One of ordinary skill in the art would easily recognize the potential of polypyrrol, Nitinol and electro- or magneto-responsive or –rheologic materials described in the specification as a driving means for the instant invention. As such, one of ordinary skill in the art would not require undue experimentation to use them as a driving means for the abrasive member of the instant invention, as recited in amended claim 1. Thus, the specification enables the invention as recited in claims 9-12. Accordingly, in view of the arguments presented herein, Applicants respectfully request that the rejection of claims 9-12 under 35 U.S.C. §112, first paragraph, be withdrawn.

The 35 U.S.C. §102 Rejections

Claims 1-6, 8, 13, 14-16, 18 and 19 are rejected under 35 U.S.C. §102(b) as being anticipated by **Heyman** (U.S. Patent No. 4,331,422). In addition, claims 1-6, 8, 13-18, 20-26, 30, 31, 34, 35, 36, 43, 44 and 60 are rejected under 35 U.S.C. §102(e) as being

anticipated by **Weaver** *et al.* (Pub. No. 2002/0065533 A1). These rejections are respectfully traversed.

The Examiner states that **Heyman** discloses an applicator, piezoelectric means to drive the applicator and an abrasive in water lubricant to alter tissue. The device is capable of use on stratum coreum, bone, and capable of delivering a pharmaceutical. In addition, the Examiner states that **Weaver** *et al.* discloses a device for ablating tissue and delivering pharmaceuticals using aluminum oxide, ice, or a pharmaceutical as the abrasive, providing an operatively connected collection means, and monitoring optical reflectance of the tissue (PPs 19, 24, 47, 58-59, 104-112, 115, and 128).

Heyman discloses an acoustic tooth cleaner designed for home use. The device has a reservoir to contain water and a mild abrasive, an acoustic wand tip through which the water/abrasive flows and an acoustic transducer with an impedance matching plate bonded thereto in the cone shaped applicator to oscillate the liquid prior to entering the cone (col. 6, ll. 35-55; Figs. 1-2). The acoustically oscillated mild abrasive particles are directed in a low pressure stream of water to create a scrubbing action to remove food particles, plaque and calculus from teeth surfaces, between teeth and in the gingival interproximal area (col. 2, ll. 53-58).

Weaver *et al.* disclose an apparatus used for creating microconduits by impingement of accelerated microparticles thereon for localized molecular and ionic transport to/from tissue (Abstract). The device comprises a means for accelerating a plurality of microparticles to a velocity that causes penetration into a tissue surface upon impingement thereon, a means for directing the microparticles towards a region of tissue surface and a means to allow the microparticles to impinge and to penetrate a region of the tissue surface ([0065]). The accelerating means is a pressurized gas, a pressurized flowing liquid, a vacuum, or a rapidly moving solid surface such as an impeller ([0041]-[0048]). The means to direct the microparticles is a mask such as a membrane comprising one or more microholes through which the microparticles may penetrate the tissue surface ([0068; Fig. 1]) or is a beam collimator to direct a scannable collimated beam of microparticles toward the tissue surface ([0076]; [0086]; Fig. 2). The means to allow the microparticles

to impinge and penetrate the tissue may be a gating switch or other ON/OFF means or a timing or metering device ([0079]-[0081]).

Applicants have canceled claims 3 and 60. As discussed *supra*, Applicants have amended independent claim 1 to incorporate the limitations of dependent claim 3 that is now drawn to a device to alter or ablate tissue in an individual. Thus, as recited in amended claim 1, the device comprises an abrasive member, either contacting the abrasive material disposed on the tissue or having the abrasive material attached thereon and a means to drive the applicator at a high frequency against the abrasive and/or the tissue surface.

Neither **Heyman** nor **Weaver** *et al.* teaches a device having an abrasive member. Both cited references teach a device comprising means of accelerating and of directing abrasive or microparticles toward the site of interest to at least impinge upon the site of interest. In **Heyman** and **Weaver** *et al.*, the abrasives or microparticles are neither disposed upon the tissue surface nor attached to any device member, but rather are held suspended in a fluid or as loose particulates until a means such as acoustic oscillation in combination with water pressure or such as a pressurized fluid or gas or an impeller, respectively, accelerate the abrasive/microparticles from the device toward the tissue surface.

Furthermore, claims 2-6, 8, 13-26, 30-31, 34-36, and 43-44 depend directly or indirectly from amended independent claim 1 and further limit the driving means, the abrasive, a lubricant further comprising the abrasive in the device or further limits the device with a means for delivering a pharmaceutical, and also further comprises a collection means, a control means to monitor feedback about an electrical property of the tissue and a control means to monitor feedback about an optical property of the tissue. As claim 1 is amended to incorporate a claim element novel over **Heyman** and **Weaver** et al., then the incorporation of any of these dependent claims into claim 1 cannot be anticipated by **Heyman**or by **Weaver**et al. At a minimum, absent teachings of the abrasive member disclosed in Applicants' amended claim 1, neither **Heyman** nor **Weaver** *et al.* can anticipate amended claim 1. Accordingly, Applicants request that the rejections of claims

1-6, 8, 13-26, 30-31, 34-36, and 43-44 under 35 U.S.C. §102(b) and 35 U.S.C. §102(e) be withdrawn.

The 35 U.S.C. §103(a) Rejections

Claims 27, 28, 32, 37, 50 and 51 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Weaver** et al. as applied to claims 26, 31, 36 and 1 above, and further in view of **Eggers** et al. (U.S. Patent No. 6,066,134). This rejection is respectfully traversed.

The Examiner states that Weaver et al. disclose the claimed invention except for monitoring feedback using the heartbeat or a thermal property of the tissue, crystallized pharmaceuticals and absorptive cotton as a collector. The Examiner further states that Eggers et al. teach monitoring feedback using a heartbeat and a thermal property of the tissue to perform a safe ablation procedure. The Examiner states that it would have been obvious to one of ordinary skill in the art at the time of the invention to use teachings of **Eggers** et al. in the device of **Weaver** et al. to increase the safety of the ablation procedure for better patient outcome. The Examiner also states that the use of crystallized pharmaceuticals in drug delivery and absorptive cotton in medical collections of liquids is notoriously well known in the art of drug delivery and sampling.

Weaver et al. is as stated by Applicants' *supra*. **Eggers** et al. teach an electrosurgical probe comprising a shaft having an electrode array, as active electrode, at its distal end, a return electrode recessed within the shaft and a connector at its proximal end for coupling the electrode array to a high frequency power supply (Abstract). **Eggers** et al. provides monitoring feedback using a heartbeat and a thermal property of the tissue to perform safe ablation of heart tissue during a revascularization procedure (col. 23, ll. 43-56).

Applicants' invention in considering amended independent claim 1 is as stated *supra*. Applicants submit that amended claim 1 is neither anticipated nor rendered obvious by **Weaver** et al. **Weaver** et al. specifically teach devices to accelerate abrasive/microparticles to impinge on a tissue and neither teach nor suggest using an abrasive member in contact with an abrasive material on the tissue or having an abrasive

material attached. In considering Weaver et al. one of ordinary skill in the art would find no motivation to include an abrasive member that alters or ablates layers of tissue. **Weaver** et al. teach that methods of transdermal drug delivery, including laser ablation of the stratum corneum or mechanical alteration of the skin, are disadvantageous because of the degree of ablation is difficult to control, the rate of transport of molecules tends to diminish rapidly with increasing molecular size, pain, discomfort or irritation at the site of ablation and the cost of equipment ([0007]; [0009]). The combination of Eggers et al. with Weaver et al. does not remedy the deficiency in Weaver et al. Therefore, amended claim 1 is non-obvious over Weaver et al. in view of Eggers et al.

Claims 26-28, 31, 32, 36, 37, 50 and 51 depend directly or indirectly from amended claim 1 and further limit the delivery means for the pharmaceutical, the device as comprising a collection means, and as further comprising means to monitor an electrical property and a thermal property, respectively. If amended claim 1 is not rendered obvious by the combination of Weaver et al. with Eggers et al., then neither are claims 26-28, 31, 32, 36, 37, 50 and 51 rendered obvious by the combination.

Accordingly, in view of the amendments and arguments presented herein, Applicants request that the rejection of claims 27, 28, 32, 37, 50 and 51 under 35 U.S.C. §103(a) be withdrawn.

Claim 29 is rejected under 35 U.S.C. §103(a) as being unpatentable over **Weaver** et al. as applied to claim 20 above, and further in view of **Unger** (U.S. Patent No. 6,416,740). This rejection is respectfully traversed.

The Examiner states that Weaver et al. discloses the claimed invention except for a reservoir with a permeable membrane to release the pharmaceutical. The Examiner also states that Unger teaches the use of a permeable membrane to release the pharmaceutical in a patch applied to the skin of a patient (col. 69, ll. 11-14). Thus, the Examiner states that it would have been obvious to one of ordinary skill in the art at the time of the invention to use teachings of **Unger** in the device of **Weaver** et al. in order to provide a convenient patch for drug delivery through the skin.

Weaver et al. is as stated by Applicants' *supra*. **Unger** teaches an acoustically active targeted therapeutic delivery system where ultrasound enhances delivery of the therapeutic (Abstract). The therapeutic, e.g., steroid prodrugs, together with a penetration enhancer may be administered transdermally in a patch or reservoir with a permeable membrane in a patch applied to the skin of a patient (col. 69, ll. 11-14).

Applicants' invention in considering amended independent claim 1 is as stated *supra*. Claim 29 depends directly from dependent claim 20 which depends from amended claim 1. Claim 20 further limits the device of amended claim as comprising a means to deliver a pharmaceutical, whereas claim 29 further limits said delivery means to a reservoir containing the pharmaceutical and comprising a membrane permeable to the pharmaceutical. Again amended claim 1 is novel and non-obvious over **Weaver** et al. as discussed supra. The combination with Unger does not remedy the deficiency in Weaver et al. Therefore, dependent claim 29 also is inventive over **Weaver** et al. in view of **Unger**. Accordingly, in view of the amendments and arguments presented herein, Applicants respectfully request that the rejection of claim 29 under 35 U.S.C. §103(a) be withdrawn.

Claims 61 and 62 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Weaver** et al. as applied to claim 60 above, and further in view of **Melbouci** *et al.* (U.S. Patent No. 6,562,090). This rejection is respectfully traversed.

The Examiner states that Weaver et al. discloses the claimed invention except for using a lubricant of water and glycerol with the abrasive. The Examiner also states that Melbouci et al. teach using water and glycerol with a lubricant to provide a stabilized suspension of abrasive in lubricant (claim 1). Thus, the Examiner states that it would have been obvious to one of ordinary skill in the art at the time of the invention to use teachings of **Melbouci** et al. in the device of **Weaver** et al. in order to facilitate the use of the abrasive.

Weaver et al. is as stated by Applicants' *supra*. **Melbouci** et al. disclose a fluid abrasive for dentifrice systems, i.e., toothpastes, that may comprise the abrasive, a water-swellable or water-soluble polymer and water mixed with glycerol (col. 3, ll. 10-44).

Neither **Weaver** et al. nor **Melbouci** et al. teach that the lubricant is electrically conductive as recited in amended claim 62.

Applicants' invention is as discussed supra. Applicants have canceled claim 60 and amended dependent claims 61-62 to depend from dependent claim 19 which depends from amended claim 1. Claims 61-62 limit the lubricant in claim 19 to glycerol and water and to an electrically conductive lubricant, respectfully. As discussed supra, **Weaver** et al. does not anticipate nor does it render amended claim 1 obvious. The combination with **Melbouci** et al. does not remedy the deficiency in **Weaver** et al. Therefore, claims 61-62, which depend indirectly from amended claim 1, also are non-obvious over **Weaver** et al. in view of **Melbouci** et al. Accordingly, in view of the amendments and arguments presented herein, Applicants respectfully request that the rejection of claims 61-62 under 35 U.S.C. §103(a) be withdrawn.

This is intended to be a complete response to the Office Action mailed September 01, 2004. Applicant submits that the pending claims are in condition for allowance. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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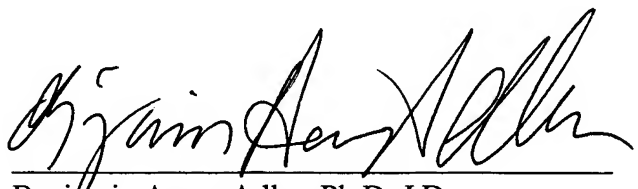

Benjamin Aaron Adler, Ph.D.,J.D.
Registration No. 35,423
Counsel for Applicant

ADLER & ASSOCIATES
8011 Candle Lane
Houston, Texas 77071
(713) 270-5391 (tel.)
(713) 270-5361 (fax)
badler1@houston.rr.com